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Dear colleagues

EFSA on Aspartame, December 2013

The *Scientific Opinion on the Re-Evaluation of Aspartame (E 951) as a Food Additive*, issued by EFSA on 10th December 2013 (in response to the European Commission, Question No EFSA-Q-2011-00406¹), represents a change from the seriously flawed draft issued by the European Food Safety Authority's ANS panel on 8 January 2013, but the changes are inconsequential.

A central argument in my critique of the January draft assessment was that the criteria by which the individual studies were interpreted were 'consistently inconsistent'.² The EFSA Panel opportunistically accepted at face value most of the studies that suggested that aspartame is harmless, while entirely discounting every single study that suggested aspartame may be harmful, even though the quality, power and sensitivity of many of the studies that were discounted were markedly superior to those of the contrary studies deemed reliable.

The December *Opinion* reproduced almost exactly the same opportunism, but with slight differences. In Table 1 below I specify the number of studies that provided no indication that aspartame is harmful. I differentiate the total into two columns of those the EFSA Panel deemed reliable and those it deemed unreliable, for both the January and December documents. Table 2 provides similar figures but for all those studies that did indicate that aspartame might be harmful.

Table 1: EFSA's interpretation of the reliability of studies *not* indicating harm, by number of studies

	Number of studies reviewed	Number treated as reliable	Number treated as unreliable
Jan 2013	83	80	3
Dec 2013	66	53	13

¹ Available at <http://www.efsa.europa.eu/en/efsajournal/pub/3496.htm>

² Available at <https://www.sussex.ac.uk/webteam/gateway/file.php?name=em-letter-to-efsa-on-aspartame-20feb2013.pdf&site=25>

Table 2: EFSA’s interpretation of the reliability of studies indicating possible harm, by number of studies

	Number of studies reviewed	Treated as reliable	Treated as unreliable
Jan 2013	27	0	27
Dec 2013	55	0	55

These tables show that the EFSA panel twice reached the conclusion that aspartame is safe, not by consistently applying uniformly critical standards to the evidence from all studies, but by routinely forgiving almost all the shortcomings of favourable studies yet being unremitting critical of all the studies suggesting any possible risks. The panel’s overall conclusion is driven more by the panel’s biased interpretative assumptions than by the evidence adduced.

In the panel had taken a genuine position of ethical, social and policy neutrality, it might have been equally sensitive to possible false negatives in Table 1 and possible false positives in Table 2. If it had actively adopted a pro-public health position, it would have given greater attention to potential false negatives than false positives. Instead it has taken a pro-industry view by being massively more critical of studies suggesting possible harm, than of their opposites.

The main change that has taken place between January and December is that the EFSA panel is marginally more critical of a few of the weakest studies listed in Table 1. In January, the panel only discounted 3 out of a total of 83, whereas in December, 13 of 66 were discounted.

As Table 2 however shows, on both occasions, the EFSA panel discounted every single study that purported to suggest possible harm. Between the cut-off dates for the January and December assessments, they evaluated 28 further studies that indicated possible harm from aspartame. In January 27 out of 27 were discounted; by December the number deemed unreliable had risen to 55 out of 55. Each and every study included in Table 2 was judged to be unreliable.

The shortcomings of the studies that suggested aspartame is harmless (which were deemed reliable) were often far greater than those of studies suggesting that aspartame may cause harm (which were deemed entirely unreliable). The benchmarks of credibility were therefore distinctly asymmetric, in a way that favours the chemical and food industry rather than consumer protection.

For example: the EFSA Panel discounted as entirely unreliable the results of the only non-commercially funded long-term aspartame rodent feeding studies conducted that the Ramazzini Foundation published this century. In contrast, studies conducted in the 1970s by, or under contract to, aspartame’s commercial sponsor (G D Searle) were shown to have been incompetently conducted and misleadingly reported but EFSA treats them as unproblematically reliable. The failure to acknowledge the very serious shortcomings in at least 15 of the early studies is especially troubling given that I provided EFSA, in response to a specific request from EFSA in 2011, with detailed evidence – in the form of photocopies of original documentation – which

showed for example that “Observation records indicated that animal A23LM was alive at week 88, dead from week 92 through week 104, alive at week 108, and dead at week 112.”³

In the rebuttal I provided to EFSA on 22 February 2013 to its draft review, I again drew the Panel’s attention to the reasons why the apparent findings of many of Searle’s studies were seriously unreliable, but a collective set of blind eyes have been turned to the evidence showing that at least 15 of the initial portfolio of studies cannot be relied upon. Nonetheless, studies E11, E33-34, E40, E41, E43 and E70 are treated as if reliably indicating that aspartame is safe.

If the EFSA panel’s criteria of appraisal had been symmetrical between possible false positives and false negatives, and reasons for discounting studies had been consistently applied, then the numbers of studies deemed unreliably reassuring would have risen by at least 15.

In 1996 Ralph Walton, of Northeastern Ohio Universities College of Medicine, reported that “Of the 166 studies felt to have relevance for questions of human safety, 74 had Nutrasweet® industry related funding and 92 were independently funded. One hundred percent of the industry funded research attested to aspartame’s safety, whereas 92% of the independently funded research identified a problem.”⁴ Extending that analysis to all the studies discussed this year by the EFSA Panel reveals that it remains the case that 100% of the industry-funded studies suggest that aspartame is harmless, whereas the percentage of independently-funded studies suggesting possible risks has risen to 97%.

EFSA’s claim that aspartame is safe has therefore been reached only by assuming that the vast majority of studies in its favour are reliable, though they have almost all been commercially funded, while every single one of the studies suggesting that aspartame might cause some kind of harm are deemed unreliable, even though they have all been funded non-commercially. Those assumptions are biased against consumer protection, even though EFSA’s responsibility is to protect consumers.

EFSA’s credibility has been seriously damaged, while the ANS Panel has lost whatever little credibility it might previously have had. As EFSA is failing to meet its responsibility to protect consumers from food-borne risks, the responsibility for sorting this mess out falls to the European Commission, the European Parliament, the Council of Ministers and to the EU Member States

Yours faithfully,



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³ Bressler J et al, *Establishment Investigation Endorsements, of Searle Laboratories Division of G.D. Searle, Chicago, for the Bureau of Foods*, 18th July 1977 and 7th August 1977 7 Aug 1977 p. 2

⁴ R G Walton, *Survey of Aspartame Studies: Correlation of Outcome and Funding Sources*, 1996, available at http://dottal.org/DIE%20DIE/survey_of_aspartame_studies.htm